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`Applicant Disclosed Prior Art

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/081,705
Filing Date: February 21, 2002
Appellant(s): CLASSEN, JOHN BARTHELOW

Evelyn McConathy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 31, 2008, appealing from the Office action mailed August 31, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0039990	Stanton	4-2002
5,991,751	Rivette	11-1999
6,458,958	D'Ambra	10-2002
5,678,234	Colombo	10-1997
6,018,714	Risen	1-2000
3,885,566	Jacob	5-1975

Examiner Notes: Applicant disclosed prior art has also been relied upon as evidence.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 250, 256, 257, 270, 271, 272, 273, 274, 275, 276, 278, 281, 282, 285, 286, 287-290, 292 and 294-298 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant disclosed prior art (ADPA) in view of Pub No 2002/0039990 (Stanton), hereafter Stanton and

further in view of Pat No 5,991,751 (Rivette et al), hereafter Rivette. and further in view of US Pat No 6,458,958 (D'Ambra et al), hereafter D'Ambra.

Claim 250, 256, 270, 271, 274, 275, 278, 280, 287-290, 292, 293, 294 and 295-297:

ADPA discloses:

accessing one or more data sources, wherein at least one data source comprises adverse event data

[specification paragraph 32]

Because of the large volume of data that they contain, preferred adverse event databases may include those of insurance companies, managed care organizations, pharmaceutical and medical device manufacturers and/or distributors, public health departments, hospitals and the like. Typically, each adverse event recorded in such databases links the adverse event with demographic information such as but not limited to, the age, sex and race and, frequently, one or more physical condition factors of the individual that experienced the essential adverse event. The result is that adverse event database 12 may contain thousands or even millions of items of data. Such vast repositories of information enable the data to be analyzed to generate statistically relevant and reliable information relating to age, gender, racial, physical condition or other subgroup. The essential adverse event database 12' is a refinement of the adverse event data procured from the adverse event database 12, based upon selection of adverse data that is "essential" as defined below

Examiner notes that particularly adverse event databases in public health departments anticipates the claimed adverse event data.

ADPA discloses the elements of the claimed invention as noted above but does not disclose analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device. **Stanton discloses analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device**

[Stanton paragraph 119]

Interpatient variability is the rule, not the exception, in clinical therapeutics. One of the best sources of information on interpatient variability is the nurses and physicians supervising the clinical trial who accumulate a body of first hand observations of physiological responses to the drug in different normal subjects or patients. Evidence of interpatient variation in response can also be measured statistically, and may be best described by statistical measures that examine magnitude of response (beneficial or adverse) across a large number of subjects.

[Stanton paragraph 134]

Methods for diagnostic tests are well known in the art. Generally in this invention, the diagnostic test involves determining whether an individual has a variance or variant form of a gene that is involved in the disease or condition or the action of the drug or other treatment or effects of such treatment. Such a variance or variant form of the gene is preferably one of several different variances or forms of the gene that have been identified within the population and are known to be present at a certain frequency. In an exemplary method, the diagnostic test involves performed by amplifying a segment of DNA or RNA (generally after converting the RNA to CDNA) spanning one or more variances in the gene sequence. Preferably, the amplified segment is <500 bases in length, in an alternative embodiment the amplified segment is <100 bases in length, most preferably <45 bases in length. In many cases, the diagnostic test is performed by amplifying a segment of DNA or RNA (cDNA) spanning a variance, or even spanning more than one variance in the gene sequence and preferably maintaining the phase of the variances on each allele. The term "phase" means the association of variances on a single copy of the gene, such as the copy transmitted from the mother (maternal copy or maternal allele) or the father (paternal copy or paternal allele). It is apparent that such diagnostic tests are performed after initial identification of variances within the gene.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify ADPA to include analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device as taught by Stanton for the purpose of determining possible adverse effects of a drug.

The combination of ADPA and Stanton discloses **identifying at least one previously unreported essential adverse event associated with the product or device from the adverse**

event data, and then responsive to identifying of the essential adverse event, identifying at least one previously unreported method of use for the product or device

[Stanton paragraph 18]

Adverse responses to drugs constitute a major medical problem, as shown in two recent meta-analyses (Lazarou, J. et al, Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies, JAMA 279:1200-1205, 1998; Bonn, Adverse drug reactions remain a major cause of death, Lancet 351:1183, 1998). An estimated 2.2 million hospitalized patients in the United Stated had serious adverse drug reactions in 1994, with an estimated 106,000 deaths (Lazarou et al.). To the extent that some of these adverse events are due to genetically encoded biochemical diversity among patients in pathways that effect drug action, the identification of variances that are predictive of such effects will allow for more effective and safer drug use.

Examiner notes that adverse reactions to drugs that result in death anticipates the claimed essential adverse event

The combination of ADPA and Stanton discloses **creating a database of proprietary essential adverse event information the database storing data regarding the at least one novel essential adverse event**

[Stanton paragraph 831]

The subject will not be identified by name or other any identifying characteristic in any study reports, and these reports will be used for research purposes only the study sponsor, its designee(s), and various Government Health Agencies may inspect the records of this study. All relevant demographic and historical data regarding patient drug response will be recorded in an anonymized database.

The combination of ADPA and Stanton discloses the elements of the claimed invention as noted above but does not disclose wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or patent publication. Rivette discloses wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or

patent publication [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of above references to include wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or patent publication as taught by Rivette for the purpose of managing an inventor's database of intellectual property.

The combination of ADPA, Stanton and Rivette disclose documenting inventorship of the at least one method of use for the product or device [Rivette: abstract]

The combination of ADPA, Stanton and Rivette discloses the elements of the claimed invention as noted above but does not disclose wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warnings about the essential adverse event, providing instructions for avoiding an essential adverse event and any combination thereof. D'Ambra discloses wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warnings about the essential adverse event, providing instructions for avoiding an essential adverse event and any combination thereof [col 1, lines 60-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the above limitation(s) for the purpose of warning the public of life threatening side effects associated with the use of a product [col 1, lines 50-65].

Claims 257, 281 and 282:

The combination of ADPA, Stanton and Rivette disclose the elements of claim 250 as noted above but does not disclose sales data. Official Notice is taken that sales data is well-known and expected in the art. It would have been obvious to one of ordinary skill in the art at

the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information for the purpose of determining the value of commercializing a product.

Claims 272, 273 and 276:

The combination of ADPA, Stanton and Rivette disclose wherein the novel method of use is a restricted use in at least one population subgroup when there is observed to be high risk of at least one adverse event associated with exposure to or use of the product or device [Stanton, paragraph 90]

Claims 251, 252, 254, 258 and 279 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette and D'Ambra and further in view of US Pat No 5,678,234 issued to Colombo et al (hereafter Colombo), as best examine is able to ascertain.

Claims 251, 252, 254 and 279:

The combination of ADPA, Stanton, Rivette and D'Ambra discloses the elements of claim 250 as noted above but does not disclose determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event. Colombo discloses determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event [col 3, lines 60-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include determining value of commercializing the

at least one new characteristic or use determined from the at least one identified essential adverse event as taught by Colombo for the purpose of making a profit.

Claim 258:

Dimino'Ambra discloses a drug interaction [col 1, lines 50-65]

Claims 253 and 255 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo and further in view of US Pat No 6,018,714 issued to Risen et al (hereafter Risen), as best examiner is able to ascertain.

Claims 253 and 255:

The combination of ADPA, Stanton, Rivette, D'Ambra and Colombo discloses the elements of claims 250-252 as noted above but does not disclose the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information. Risen discloses the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information as taught by Risen for the purpose of deriving income from intellectual property.

Claims 259, 260, 261-269, 277, 283, 284 and 291 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton and Rivette and Risen.

Claims 259 and 277:

Regarding claim 259, Official Notice is taken that raw commercial or sales data is well-known and expected in the art.

Claim 260:

Regarding claim 260, Official Notice is taken that proprietary information is well-known and expected in the art.

Claims 261-263, 266 and 267:

Regarding claim 261, Official Notice is taken that a medical product is well-known and expected in the art.

Claims 264, 265, 268 and 269:

Regarding claim 264, Official Notice is taken that a non-medical product is well-known and expected in the art.

Claims 283 and 284:

Regarding claim 283, Official Notice is taken that product exposure times are well-known and expected in the art.

Claim 291:

Regarding claim 291, Official Notice is taken that date of inventorship is well-known and expected in the art.

Claims 299 and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton and Rivette as applied to claim 250 above, and further in view of US Pat No 3,885,566 (Jacob), hereafter Jacob.

Claims 299 and 300:

The combination of ADPA, Stanton and Rivette disclose the essential elements of the claimed invention as noted above but does not disclose wherein the novel use further comprises providing novel printed product safety information in connection with product packaging. Jacob providing novel printed product safety information in connection with product packaging [col 1, lines 35-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include providing novel printed product safety information in connection with product packaging as taught by Jacob for the purpose of ensuring the safety of disposable diapers.

(10) Response to Argument

Appellant Argues:

Appellant states on page 13 "Thus none of the limitations is met by the Stanton reference, which offers neither a written description, nor a printed publication BEFORE the earliest effective filing date of Applicant's invention, and is quite simply not permitted prior art against Applicant's invention. As such all rejections based on Stanton as the underlying reference must therefore fail, as being based on an improper prior art reference. Accordingly, Applicant asks that all 103 rejections be removed and the Applicant's application be found patentable."

Examiner Responds:

Examiner is not persuaded.

Vincent P. Stanton JR filed patent application 09/733,651 on December 7, 2000. The patent application was published in April 4, 2002 as Pub No. US 2002/0039990. Stanton claimed benefit under at least one of U.S.C. 119(e), 120 and 365(c). However, for this analysis, reliance on above claimed benefit(s) is not necessary to show that patent application 09/733,651 filed in December 7, 2000 is proper prior art under 102(e1).

MPEP § 706.02(f)(1) Examination Guidelines for Applying References Under 35 U.S.C. 102(e) states the following:

Example 1: Reference Publication and Patent of 35 U..S.C. 111(a)

Application with no Priority/Benefit Claims

For reference publications and patents of patent applications filed under 35 U.S.C. 111(a) with no claim for the benefit of, or priority to, a prior application, the prior art dates under 35 U.S.C. 102(e) accorded to these references are the earliest effective U.S. filing dates. Thus, a publication and patent of a 35 U.S.C. 111(a) application, which does not claim any benefit under either 35 U.S.C. 119(e), 120 or 365(c), would be accorded the applications actual filing date (emphasis added) as its prior art date under 35 U.S.C. 102(e).

Considering once again Stanton's application for patent, the 102(e) date is at least the filing date of the nonprovisional patent application which is earlier than the earliest priority claimed by applicant, i.e., filing of provisional patent application no. 60/270,697 filed on February 22, 2001. Stanton is prior art regarding the present application.

Further, Stanton is proper prior art under 35 U.S.C. 103(a) because the assignee of the Stanton application for patent is Variagenics Inc and the assignee for the present application is

Classen Immunotherapies. The Stanton reference cannot be disqualified under 35 U.S.C. 103(c) because the Stanton reference and the present application were not commonly owned or subject to an obligation of common assignment at the time the invention was made.

Appellant Argues:

Appellant states on page 14, "Nevertheless, the present invention is not intended to encompass pharmacogenomic techniques for screening."

Examiner Responds:

Examiner is not persuaded.

In response to appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., pharmacogenomic techniques for screening) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (fed. Cir. 1993).

Appellant Argues:

Appellant states in the third paragraph of page 15, "By contrast, however, although Stanton at paragraph [0019] and [0014] refers to adverse events, Stanton never states or suggests that the adverse event is essential as defined by Applicant nor that it is new or novel or previously unreported or unknown as would be required of an inventor conceiving of an proprietary invention."

Examiner Responds:

Examiner is not persuaded.

The specification does not provide a specific and deliberate definition of essential adverse event as alleged by Appellant.

The specification describes essential adverse event as follows:

Paragraph [0035]
Through operation of system 10 and the other systems described herein, the data extracted from the adverse event database 12 is analyzed by suitable programming of processor 18 to produce useful essential adverse event information that collected into essential adverse event database 12 and storable inn essential adverse event information storage device 22. For example, the adverse event database stores information on frequency of **essential adverse events, such as but not limited to, death, illness, hospitalization, office visits, disability, missed work, medical costs, abnormal lab results and surgeries receiving the product or device in question,** and this information can be compared to the observed adverse event rate in the same persons before receiving the essential product or in persons of similar characteristics (i.e. a control group). The analysis is performed on different exposure rates including, but not limited to the amount, duration and timing of exposure to the product or device.

The specification fails to specifically and deliberately define essential adverse event because the specification merely provides examples of essential adverse event data. It is unclear what applicant is attempting to include with the language "such as, but not limited to." Furthermore, a skilled artisan would not be able to make and use the invention because the skilled artisan would be confused by the stipulation that essential adverse events include missed work, office visits and medical costs and such <u>missed work, office visits and medical costs</u> (emphasis added) require manufacturers and/or distributors to provide a notice or warning attached to a product or device to avoid criminal and/or civil liability [specification paragraph 4].

During examination, the MPEP requires an examiner to give claims their broadest reasonable interpretation in light of the specification. As the specification has failed to provide a specific and deliberate definition of essential adverse event data, essential adverse data must be

interpreted in the context of the claims themselves, dictionary definitions (specialized and generic), and the level of ordinary skill (from treatises, a search of the prior art and other specialized information sources) to determine the broadest reasonable interpretation of the claim terminology.

Examiner maintains that following disclosures by Stanton anticipates the claimed essential adverse event data.

[Stanton paragraph 18]

Adverse responses to drugs constitute a major medical problem, as shown in two recent meta-analyses (Lazarou, J. et al, Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies, JAMA 279:1200-1205, 1998; Bonn, Adverse drug reactions remain a major cause of death, Lancet 351:1183, 1998). An estimated **2.2 million hospitalized patients in the United Stated had serious adverse drug reactions in 1994,** with an estimated 106,000 deaths (Lazarou et al.). To the extent that some of these adverse events are due to genetically encoded biochemical diversity among patients in pathways that effect drug action, the identification of variances that are predictive of such effects will allow for more effective and safer drug use.

[Stanton paragraph 45]

The term "deleterious effects" refers to physical effects in a patient caused by administration of a treatment which are regarded as medically undesirable. Thus, for example, deleterious effects can include a wide spectrum of **toxic effects injurious to health such as death of normal cells** when only death of diseased cells is desired, nausea, fever, inability to retain food, dehydration, damage to critical organs such as renal tubular necrosis, fatty liver or pulmonary fibrosis, among many others. In this regard, the term "contra-indicated" means that a treatment results in deleterious effects such that a prudent medical doctor treating such a patient would regard the treatment as unsuitable for administration. Major factors in such a determination can include, for example, availability and relative advantages of alternative treatments, consequences of non-treatment, and permanency of deleterious effects of the treatment.

[Stanton paragraph 89]

The "action" of a drug refers to its effect on biological products within the body. The action of a drug also refers to its effects on the signs or symptoms of a disease or condition, or effects of the drug that are unrelated to the disease or condition leading to unanticipated effects on other processes. **Such unanticipated processes often lead to adverse events or toxic effects. The terms "adverse event" or "toxic" event" are known in the art and include, without limitation, those listed in the FDA reference system for adverse events.**

In summary, examiner maintains that the above disclosures by Stanton anticipates the claimed essential adverse data because Stanton discloses:

(1) 2.2 million hospitalized patients in the United States had serious adverse drug reactions in 1994

(2) toxic effects injurious to health such as death of normal cells

(3) adverse event or toxic event are known in the art and include without limitation those listed in the FDA reference system for adverse events

Examiner notes that above interpretation of the Stanton teachings is in line with the suggestion in applicant's specification which states:

[specification paragraph 5]

The government has failed to establish mechanisms by which products and devices are adequately screened for safety, i.e., for the possibility of essential adverse events which could affect the safety of the patient using the product or device. This is particularly true for medical products and devices. The screening that is conducted by manufacturers and/or distributors of such products and devices is typically small in scale and incomplete for all possible adverse events. Consequently, until the present invention, there has been a need in the art for reliable screening methods to eliminate or minimize the possibility of an essential adverse event that could affect a patient or consumer using a product or device, so that the consumer can trust that the product or device is "safe."

Appellant Argues:

Appellant states on page 15 that "In marked contrast, according to Applicant's invention there is no clinical trial required."

Examiner Responds:

Examiner is not persuaded.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which Appellant relies (i.e., the requirement for clinical trial is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant Argues:

Appellant states on page 16, "Accordingly, because Stanton requires a gene database (paragraph 99) as a critical element of the invention, which element is expressly excluded from Applicant's invention (paragraph 103), Stanton is not prior art to Applicant's invention. The Stanton database is not an "adverse event dataset " as described by Classen and does not mention a novel essential adverse event.

Examiner Responds:

Examiner is not persuaded.

In response to appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., gene database) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Geuns,

988 F.2d 1181, 26 USPQ2d 1057 (fed. Cir. 1993). Furthermore, as above, examiner shows that Stanton anticipates the claimed "essential adverse event database."

Appellant Argues:

Furthermore, on pages 17-24 of the Appeal Brief, Appellant argues that Rivette and D'Ambra do not correct the deficiencies of Stanton.

Examiner Responds:

Examiner is not persuaded. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where he rejections are based on combinations of references. See In re Keller, 642 F.2d413, 208 USPQ871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the above Office action clearly maps Rivette and D'Ambra to the claim limitations of claim 1 and provides a reason why one of ordinary skill in the art would have been motivated to combine the references.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Conferees:

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